

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Patent Application of |) | |
| Ronald MATHISON et al. |) | Group Art Unit: Not Yet Assigned |
| Application No.: Not Yet Assigned |) | Examiner: Not Yet Assigned |
| Filed: February 9, 2004 |) | Confirmation No.: Not Yet Assigned |
| For: PEPTIDES FOR TREATMENT OF |) | |
| INFLAMMATION AND SHOCK |) | |

**FIRST INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge \$_____ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of \$_____ is enclosed for the fee due.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: February 9, 2004

By: _____

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Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. All of the listed documents were previously made of record in prior Application Serial No. 09/051,395, filed May 8, 1998, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120. Therefore, copies of the below listed documents are not enclosed.

U.S. PATENT DOCUMENTS

1. GALLAHER, U.S. Patent No. 4,880,779, issued on November 14, 1989.

FOREIGN PATENT DOCUMENTS

1. WIEDEMAN et al., International Publication No. WO 92/11858, published on July 23, 1992.

NON-PATENT DOCUMENTS

1. MATHISON et al., "Neural regulation of neutrophil involvement in pulmonary inflammation," *Comp. Physiol.*, 1993, pp. 39-48, vol. 106C, no. 1, Springer-Verlag Heidelberg, Heidelberg, Germany;
2. Bachem Feinchemikalien AG, Hauptstrasse 144, CH-4416 Bubendorf/Switzerland, *Bachem Catalog S13*, 1993, pages 203 and 522, Abstract No. XP002051006;
3. ABDERHALDEN et al., "Ubr das Verhalten von Tetrapeptiden gegenüber Erepsin und Trypsin, an deren Aufbau Glykokoll (2 Mol), 1(+)- Alanin (1 Mol) und 1(-)- Tyrosin (1 Mol) beteiligt sind," *Fermentforschung*, 1942, pps. 98-114, vol. 16;
4. SLOOTSTRA, "Structural aspects of antibody-antigen interaction revealed through small random peptide libraries", *Molecular Diversity*, 1996, pp. 87-96, vol. 1, Kluwer Academic Publishers, Basel, Switzerland;
5. MATHISON et al., "Submandibular glands: novel structures ...", *Can. J. of Physiol. Pharmacol.*, 1997, pp. 407-413, vol. 75, Abstract No. XP992051009, National Research Council of Canada, Ottawa, Ontario, Canada;
6. GRANT, "Synthetic Peptides: A User's Guide," Freeman & Company, 1992, page 53;
7. WILKES et al., "Critical Ionizing Groups in Aeromonas Neutral Protease," *J. Biol. Chem.*, 1988, pp. 1821-1825, vol. 263, no. 4, Walter de Gruyter, Berlin, Germany;
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Bethesda, MD;
9. MATHISON et al., "Removal of the submandibular glands increases the acute hypotensive response to endotoxin, *Circulatory Shock*, 1993, pp 52-58, vol. 39, Wiley-Liss, Inc., New York, New York;
 10. NGO et al., "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, *Ed. K. Merz and L. Le Grand*, BirkHauser, Boston, MA, pp. 491-495;
 11. RUDINGER, "Characteristics of the amino acids as components of a peptide hormone sequence," Peptide Hormones, Ed. J.A. Parsons, National Institute for Medical Research, Mill Hill, London, University Park Press, Baltimore, MD, pp. 1-7, 1976;
 12. BARKA, "Biologically Active Polypeptides in Submandibular Glands," *The Journal of Histochemistry and Cytochemistry*, 1980, pp. 836-859, vol. 28, no. 8, The Histochemical Society/High Wire Press, New York, New York;
 13. BOYER et al., "Une fonction non exocrine de la glande sous-maxillaire," *Annales d'Endocrinologie*, 1991, pp. 307-322, vol. 52, Paris, France;
 14. MATHISON et al., "Neuroendocrine regulation of inflammation and tissue repair by submandibular gland factors," *Immunology Today*, 1994, pp. 527-531, vol. 15, no. 11, Elsevier Science, Ltd., England;

15. EPSTEIN et al., "The role of saliva in oral health and the causes and effects of xerostomia," *The Canadian Dental Association Journal*, 1992, pp. 217-221, vol. 58;
16. KINGSNORTH et al., "Epidermal growth factor increases tensile strength in intestinal wounds in pigs," *Br. J. Surg.*, 1990, pp. 409-412, vol. 77, John Wiley & Sons, Inc., Chichester, England & NY;
17. SKINNER et al., "Influence of Desalivation on Acid Secretory Output and Gastric Mucosal Integrity in the Rat," *Gastroenterology*, 1981, pp. 335-339, vol. 81, no. 2, WB Saunders, Philadelphia, PA;
18. GRAY et al., "Role of salivary epidermal growth factor in the pathogenesis of Barrett's columnar lined oesophagus," *Br. J. Surg.*, 1991, pp. 1461-1466, vol. 78, John Wiley & Sons, Inc., Chichester, England and New York;
19. KURACHI et al., "Evidence for the involvement of the submandibular gland epidermal growth factor in mouse mammary tumorigenesis," *Proc. Natl. Acad. USA*, 1985, pp. 5940-5943, vol. 82, National Academy of Sciences, Washington, D.C.;
20. JONES et al., "Epidermal growth factor secreted from the salivary gland is necessary for liver regeneration," *Gastrointest. Liver Physiol.*, 1995, pp. 872-878, vol. 31, The American Physiological Society, Bethesda, Maryland;
21. AMANO et al., "Expression and Localization of Hepatocyte Growth Factor in Rat Submandibular Gland," *Growth Factors*, 1994, pp. 145-151, vol. 10, Harwood Academic Publishers GmbH, Singapore;

22. TSUTSUMI et al., "A physiological Role of Epidermal Growth Factor in male Reproductive Function," *Science*, 1986, pp. 975-977, vol. 233, Amer. Assn. For the Advancement of Science, Washington, D.C.;
23. TSUTSUMI et al., "The uterine growth-promoting action of epidermal growth factor and its function in the fertility of mice," *Journal of Endocrinology*, 1993, pp. 437-443, vol. 38, Endocrine Society, Baltimore, MD.;
24. ROSINSKI-CHUPIN et al., "The Gene Encoding SMR1, a Precursor-Like Polypeptide of the Male Rat Submaxillary Gland, Has the Same Organization as the Preprothyrotropin-Releasing Hormone Gene," *DNA and Cell Biology*, 1990, pp. 553-559, vol. 9, no. 8, Mary Ann Liebert, Inc, New York, New York;
25. ROSINSKI-CHUPIN et al., "High level of accumulation of a mRNA coding for a precursor-like protein in the submaxillary gland of male rats," *Proc. Natl. Acad. USA*, 1988, pp. 8553-57, vol. 85, National Academy of Sciences, Washington, D.C.;
26. KEMP et al., "Suppression and enhancement of *in vitro* lymphocyte reactivity by factors in rat submandibular gland extracts," *Immunology*, 1985, pp. 261-67, vol. 56, Elsevier Science, Ltd., England;
27. ABDELHALEEM et al., "Indentification of immunosuppressive fractions from the rat submandibular salivary gland," *Immunology*, 1992, pp. 331-37, vol. 76, Elsevier Science, Ltd., England;
28. BISSONNETTE et al., "Decentralization of the Superior Cervical Ganglia Inhibits Mast Cell Mediated TNF α -

- Dependent Cytotoxicity. 1. Potential Role of Salivary Glands," *Brain, Behavior, and Immunity*, 1993, pp. 293-300, vol. 7, Elsevier, Ltd., England;
29. CARTER et al., "Inhibition of neutrophil chemotaxis and activation following decentralization of the superior cervical ganglia," *Journal of Leukocyte Biology*, 1992, pp. 597-602, vol. 51, Society for Leukocyte Biology, Bethesda, Maryland;
30. SAITO et al., "Saliva Inhibits the Chemiluminescence Response, Phagocytosis, and Killing of *Staphylococcus epidermidis* by Polymorphonuclear Leukocytes," *Infection and Immunity*, 1988, pp. 2125-32, vol. 56, no. 8, American Society for Microbiology, Washington, D.C.;
31. RAMASWAMY et al., "Marked Antiinflammatory Effects of Decentralization of the Superior Cervical Ganglia", *Journal of Experimental Medicine*, 1990, pp. 1819-30, vol. 172, Rockefeller Univ. Press, New York, New York;
32. MATHISON et al., "Role for the Submandibular Gland in Modulating Pulmonary Inflammation following induction of Systemic Anaphylaxis," *Brain, Behavior, and Immunity*, 1992, pp. 117-129, vol. 6, Elsevier Science, Ltd., London, England.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since the documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b) no fee or statement is required.

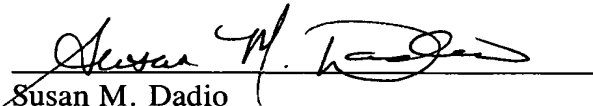
To assist the Examiner, the documents are listed on the attached form PTO-1449.
It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: February 9, 2004

By:


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Registration No. 40,373

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| Substitute for forms 1449A/PTO & 1449B/PTO FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT | ATTORNEY'S DKT NO. 024916-013 | APPLICATION NO. Not Yet Assigned |
| | APPLICANT Ronald MATHISON et al. | |
| | FILING DATE February 9, 2004 | GROUP Not Yet Assigned |

| U.S. PATENT DOCUMENTS | | | | |
|-----------------------|-----------------|----------------------|---|-------------------------------------|
| Examiner Initials | Document Number | Kind Code (if known) | Name of Patentee or Applicant of Cited Document | Issue/Publication Date (MM-DD-YYYY) |
| | 4,880,779 | | GALLAHER | 11-14-1989 |
| | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------|----------------------|---------|----------------------------------|-----------------------|
| Examiner Initials | Document Number | Kind Code (if known) | Country | Date of Publication (MM-DD-YYYY) | Translation Yes No |
| | WO 92/11858 | | PCT | 07-23-1992 | |
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| NON PATENT LITERATURE DOCUMENTS | |
|---------------------------------|---|
| Examiner Initials | Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
| | MATHISON et al., "Neural regulation of neutrophil involvement in pulmonary inflammation," <i>Comp. Physiol.</i> , 1993, pp. 39-48, vol. 106C, no. 1, Springer-Verlag Heidelberg, Heidelberg, Germany. |
| | Bachem Feinchemikalien AG, Hauptstrasse 144, CH-4416 Bubendorf/Switzerland, <i>Bachem Catalog S13</i> , 1993, pages 203 and 522, Abstract No. XP002051006. |
| | ABDERHALDEN et al., "Ubr das Verhalten von Tetrapeptiden gegenüber Erepsin und Trypsin, an deren Aufbau Glykokoll (2 Mol), 1(+)- Alanin (1 Mol) und 1(-)-Tyrosin (1 Mol) beteiligt sind", <i>Fermentforschung</i> , 1942, pps. 98-114, vol. 16. |
| | SLOOTSTRA, "Structural aspects of antibody-antigen interaction revealed through small random peptide libraries", <i>Molecular Diversity</i> , 1996, pp. 87-96, vol. 1, Kluwer Academic Publishers, Basel, Switzerland. |
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| | RUDINGER, "Characteristics of the amino acids as components of a peptide hormone sequence," <u>Peptide Hormones</u> , Ed. J.A. Parsons, National Institute for Medical Research, Mill Hill, London, University Park Press, Baltimore, MD, pp. 1-7, 1976. |
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| Examiner Signature | | Date Considered | |
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.